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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,534	02/03/2003	Catia Bastioli	13929/T/B/A	7100
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Byran Cave LLP 1290 Avenue of the Americas 33rd Floor New York, NY 10104			EXAMINER SAYALA, CHHAYA D	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/936,534

Applicant(s)

BASTIOLI ET AL.

Examiner

C. SAYALA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 102

1. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/30691.

Example 2 shows inulin and potato starch extruded with glycerol at the same temperatures. The reference therefore, meets the process and the composition.

Claim Rejections - 35 USC § 102/ Claim Rejections - 35 USC § 103

2. Claim 14 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 011663.

Claim 14 claims a mixture of inulin and /or oligofructan with thermoplastic polymers, written in a product-by-process format. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

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production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. " In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985).

See the claims in the EP patent. Claim 1 which shows a tubular membrane prepared as in claims 3, 5 and 8, which claims are pertinent to the extent of their disclosure of the mixture claimed herein, i.e. polymer and inulin, capable of being extruded.

3. Claim 14 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 93/09176.

See claims 1-5. Claim 1 describes a polysaccharide given as inulin in claim 5, which contains a moiety which will undergo polymerization. Therefore, the material is a combination of inulin and a polymer and is "thermochemically processable".

Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

4. Claim 14 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gutttag (US Patent 5346929).

See claims 1 and 11 that recite inulin with polymers. Since inulin is the same, then it is inherently "thermoplastically processable".

Claim 1 recites a synthetic polymer and a natural polymer, which claim 11 recites is an inulin; synthetic polymers are described at col. 4, lines 10-16. The claim requires two elements, inulin and thermoplastic polymers. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

5. Claim 14 is rejected under 35 U.S.C. 102(e) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Van Havernen et al. (US Patent 6313203).

The claims show a mixture of a thermoplastic polymer with inulin. See claim 4. See col. 2, lines 10-11 that describe inulin as being the polyfructose (claim 1), which is a known fact in basic chemistry. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

Claim Rejections - 35 USC § 103

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6. Claims 1, 4, 7 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leo (US Patent 5419283) and Wang (US Patent 5922379) in view of Anantharaman et al. (US Patent 5952033) and further in view of Van Haveren et al. (US Patent 6313203) and Bengs et al. (US Patent 6406530).

Both Leo and Wang teach biodegradable thermoplastic products.

Leo discloses a chew toy for pets made from a plastic material. At col 1, lines 27+ patentee states:

The preferred materials are thermoplastic blends obtained by processing starch and said thermoplastic polymers in the presence of a limited amount of water (10-40% wt. referred to the starch/water system) or of a polyol plasticizer (10-40% wt. referred to the starch/polyol system), under extrusion cooking conditions thereby to provide a melt to be extruded and transformed into pellets for use in injection moulding or to be directly injection moulded.

At col 1, line 33-40 states that the materials thermoplastic blends of starch and thermoplastic polymers in the presence of water and polyols as plasticizers, can be extruded.

Wang teaches a biodegradable protein/starch based thermoplastic composition that can be extruded and consumed by animals and. See col 8, lines 13-14, col 2, line 17. Plasticizers are shown at col 4 line 46+. The amount of starch is 20-60% (col 3, lines 63-64).

Both patents do not teach inulin. However, inulin, a polysaccharide, is known to be a stabilizer for extrudable thermoplastics. See Van Haveren et al (col 2, line 62-64

and abstract). Bengs et al. teach a mixture of starches including inulin, used in biodegradable thermoplastic materials that can be thermoplastically processable using techniques such as injection holding or extrusion. Col 1, line 32, col 2, lines 58, col 3, lines 20-21, col 4 line 66-67, col 5, lines 21-28. Note that the *mixture* of starches is given to be in an amount 33-90%.

Anantharman et al teach the use of inulin in pet food products is beneficial in an amount of at least 0.25%. See col 1, which states that inulin promotes bifido- and lacto-bacteria in the GI tract at the expense of pathogens and is very beneficial for animals and inulin has been used as a vet diet for pets. Col 1, 50-52. col 2, lines 7-12. This patent establishes that inulin has been used for pet foods and that "for pet foods, their use has been confined to specialty veterinary products such as the Eukanuba product and to pet treats. Similarly, for human foods, their use has been confined to specialty products." (Col. 2, lines 7-10).

Therefore, while Leo and Wang establish biodegradable, thermoplastically processable starch containing products have been used for pet chews, Anantharaman et al., by establishing that inulin provides benefits for the GI tract for pets, and that inulin has been used for pet treats, motivates one of ordinary skill in the art to incorporate inulin in biodegradable, thermoplastically processable products of Leo and Wang in pet products with plasticizers or glycerol, etc. In fact the patents to Bengs et al. and Van Haveren et al. show shaped, extrudable, biodegradable, inulin containing articles wherein inulin additionally acts as a stabilizer for such a thermoplastically processable

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compositions (Van Havernan et al.). Patents to Anantharaman et al. and Van Haveren et al. show inulin amounts of "at least 0.25%" and mixtures of starch including inulin between 33% to 90%, and to determine amounts for various pet chew articles would have been obvious based on such disclosure. With regard to claim 13, Leo shows a bone. With regard to claim 12, the Anantharaman et al. patent shows the extrusion temperature at col 4, line 10-15.

Summarizing:

- Leo teaches the use of thermoplastic blends of starch and polymers and polyols as plasticizers, extruded to a chew toy.
- Wang et al. teach biodegradable protein/starch thermoplastic compositions that can be extruded and consumed by animals.
- Anantharaman et al. teach the usefulness of inulin in pet foods and disclose that it has been used as a vet diet for pets.
- Van Haveren et al. disclose that inulin is a stabilizer for extrudable thermoplastics.
- Bengs et al. teach a mixture of starches including inulin, in a composition that is thermoplastically processable using extrusion techniques and injection molding.

Response to Arguments

Applicant's arguments filed 11/13/2008 have been fully considered but they are not persuasive.

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Applicant has presented claim 14 in a product-by-process format.

MPEP 2113 states as follows:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

There is no evidence that the process steps by which the product is made are unique or that the product can only be defined by the process steps. In fact, prior art shows the process to be old and known. Therefore, the product is also known by prior art.

With reference to Goehl, (the EP patent) applicant has focused on the process by which the product was made in order to establish patentability. Again, applicant is reminded that the claim in question is a product claim. Applicant's claim is drawn to an article that can be chewed on, and which contains inulin (or other fructooligosaccharides) and thermoplastic polymers, that are capable of being thermoplastically processed.

With reference to Soon-Shiang, (the WO patent) applicant's criticism that the examiner has not pointed out examples showing inulin, is not a criteria that can be used to withdraw this rejection, when the *claims of the reference* clearly anticipate the same subject matter. There is no requirement under 35 USC 102, that the reference's claimed subject matter be ignored because the patent does not show an example.

The rejections over Guttag and van Haveren are being maintained because, as explained in the rejection itself, the product can be produced by more than one process. Applicant states that the product cannot be produced without a plasticizer. This is unsubstantiated. Furthermore, applicant has listed a number of synthetic polymers in the specification at page 5, last paragraph, and therefore, the argument that Guttag shows synthetic polymers which cannot be used for the claimed invention cannot advance patentability of the claim.

With regard to the examiner missing the mark, and the fact that "one would not be motivated to use inulin because its molecular mass is so low" and that the artisan would not expect success in converting it to a thermoplastically processable material, first, the motivation has been clearly shown thus:

Both patents do not teach inulin. However, inulin, a polysaccharide, is known to be a stabilizer for extrudable thermoplastics. See Van Haveren et al (col 2, line 62-64 and abstract). Also, Bengs et al. teach a mixture of starches including inulin, used in biodegradable thermoplastic materials that can be thermoplastically processable using techniques such as injection holding or extrusion. Col 1, line 32, col 2, lines 58, col 3, lines 20-21, col 4 line 66-67, col 5, lines 21-28. Note that the mixture of starches is given to be in an amount 33-90%.

Ananthararman et al teach the use of inulin in pet food products is beneficial in an amount of at least 0.25%. See col 1, which states that inulin promotes bifido- and lacto-bacteria in the GI tract at the expense of pathogens and is very beneficial for animals and inulin has been used as a vet diet for pets.

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Assertion that examiner combines prior art references for purpose different from that envisioned by inventors does not warrant reversal of examiner's finding of obviousness.

Ex parte Raychem Corp. 17 USPQ2d 1417.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala, whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/C. SAYALA/
Primary Examiner, Art Unit 1794**

